

Exhibit 5

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**CONCERNS WITH REBATES
IN THE
MEDICARE PART D PROGRAM**



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March 2011
OEI-02-08-00050

► EXECUTIVE SUMMARY

OBJECTIVES

1. To determine the extent to which all Part D sponsors received rebates in 2008.
2. To determine the extent to which all Part D sponsors passed rebates on to beneficiaries.
3. To describe the nature of the rebates received by selected sponsors.
4. To describe the nature of selected sponsors' contractual relationships with pharmacy benefit managers (PBM).

BACKGROUND

Under the Medicare Part D program, private insurance companies, known as sponsors, provide drug coverage to beneficiaries who choose to enroll. These sponsors are responsible for reducing the cost of the program by negotiating rebates from drug manufacturers. Drug manufacturers provide rebates to increase drug sales.

Rebates can substantially reduce the cost of the Part D program; however, sponsors must accurately report these rebates for the Government and beneficiaries to receive any cost savings. Prior to this review, little information was publicly available about the extent to which sponsors receive rebates for Part D drugs and pass them on to the Government and beneficiaries. Also, little was known about the nature of rebates and the contractual relationships between sponsors and PBMs, the third-party entities that often negotiate for rebates on behalf of sponsors.

Before the beginning of each plan year, sponsors must provide the Centers for Medicare & Medicaid Services (CMS) with bids that contain information about the rebates they expect to receive. CMS uses these bids to calculate beneficiary premiums. After the close of the plan year, sponsors must provide CMS with information about the actual amount of rebates they received. CMS uses this information to determine the amount that the Government ultimately pays each sponsor for providing the benefit. If sponsors receive rebates at the sponsor level, rather than the plan level, CMS requires that sponsors allocate a portion of these rebates to each of their plans. The methods sponsors use can affect the amounts that the Government ultimately pays sponsors for providing the benefit.

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least three tiers: one for generic drugs, one for preferred brand-name drugs, and one for nonpreferred brand-name drugs. Beneficiaries paid a different copayment for drugs on each tier. For example, in one plan, beneficiaries had a \$5 copayment for generic drugs, a \$25 copayment for preferred brand-name drugs, and a \$60 copayment for nonpreferred brand-name drugs. All six sponsors received rebates for including the drugs on the brand-name preferred tiers.

Sponsors also often received rebates when they discouraged the use of competitors' drugs. As one sponsor noted, "manufacturers pay more for less competition." For example, several rebate agreements specified that a competitor's drug must have a higher copayment than that of the rebated drug. Other agreements required the sponsor to exclude a competitor's drugs from its formulary altogether. Rebates were often larger when fewer competitors' drugs were given preference on the formulary. For example, one sponsor received a 35-percent rebate when the drug was one of two preferred drugs in its class, but a 40-percent rebate when the drug was the only preferred drug in its class on the formulary.

The rebates were also dependent on other aspects of their benefit design. As noted earlier, sponsors can institute utilization management tools, such as requiring a beneficiary to seek prior authorization before covering certain drugs. Sponsors often received rebates under the condition that the rebated drug was not subject to any utilization management tools.

Finally, five sponsors received higher formulary rebates for beneficiaries eligible for the low-income subsidy than for other Part D beneficiaries. For example, one sponsor received a 20-percent rebate for drugs dispensed to low-income subsidy beneficiaries, compared to a 10-percent rebate for the same drug dispensed to other Part D beneficiaries. Manufacturers may have provided higher rebates for low-income subsidy beneficiaries as an incentive to sponsors to move these beneficiaries to the rebated drugs. It may be more difficult for sponsors to move these beneficiaries because they are not subject to the same cost-sharing requirements as other Part D beneficiaries and therefore do not have the same incentives to select preferred drugs. For example, in 2008, low-income subsidy beneficiaries paid, at most, a \$5.60 copayment for brand-name drugs and a \$2.25 copayment for generic drugs. They did not have a copayment differential between preferred and nonpreferred brand-name drugs.

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of the selected sponsors were unaware of all of the contract terms that determine the rebates they receive from drug manufacturers.

Several of the sponsors also had limited information about the rebate amounts they actually received for each drug. As one sponsor explained, its PBM provided aggregate information for all the rebates associated with each Part D plan, rather than by drug name. As a result, this sponsor did not know the amount of rebates it received for each drug.

Several sponsors and PBMs further noted that the PBM industry is extremely competitive and, as a result, information about a PBM's business practices, including the rebate contracts and the negotiated rebate amounts, is highly confidential. In fact, the PBMs in our study were, in some cases, unwilling to discuss details about their business practices in front of the sponsor.

Selected sponsors relied primarily on audits to verify the rebate amounts, and these audits were sometimes limited

The selected sponsors relied primarily on audits to verify that they received the appropriate amount of rebates and that the rebate data they reported to CMS were accurate.³³ In some cases, the scope of what the sponsor could audit was restricted. According to one sponsor's contract with its PBM, the sponsor could audit a limited number of its rebate agreements for the two quarters immediately preceding the audit. However, the contract also stated that the manufacturer had the right to deny the sponsor access to rebate agreements requested for the audit. Another PBM contract stated that the sponsor could review only a sample of rebate agreements. A third sponsor's contract with its PBM stated that the sponsor had the right to audit only certain parts of the rebate agreements. In addition, two sponsors were required to use a third-party auditing firm to perform these audits.

Selected sponsors reported that their PBMs collected fees from drug manufacturers that were not always passed on to the Part D program

Five of the six selected sponsors reported that their PBMs received fees from drug manufacturers, in addition to the fees that sponsors paid PBMs for negotiating rebates.³⁴ These fees were structured like rebates

³³ Several sponsors also explained that they conducted a broad-level data analysis to roughly check the amount of rebates that they should have received.

³⁴ The sixth sponsor reported that its PBM did not receive these fees.

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in that they were generally based on a fixed percentage of WAC. According to the contracts we reviewed, these fees were for services that the PBM provided to the manufacturers, such as negotiating rebates, calculating rebate amounts, and distributing rebates to sponsors.

The PBMs handled these fees somewhat differently. For example, two of the PBMs considered these fees to be rebates and provided them to the sponsors. As a result, these sponsors reported them to CMS and passed them on to the Government, thereby reducing the overall cost of the Part D program.

In the other three cases, the PBMs considered these fees to be for services they provided to the manufacturers and therefore they did not pass them on to the sponsors. As a result, the sponsors did not report the fees to CMS and therefore they were not passed on to the program. Specifically, the PBMs considered these fees to be bona fide service fees, which CMS does not consider price concessions if they are at fair market value. The contracts we reviewed between the sponsors and the PBMs had only limited information about these fees. Because sponsors may not always be able to verify whether these fees should be considered rebates or bona fide service fees, they may be inaccurately reporting this information to CMS.